08/187,879 01/27/94 ROBINSON

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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CLARK, D

EXAMINER	
1633	

ART UNIT	PAPER NUMBER
11	32

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/187,879	Applicant(s) Robinson et al.
	Examiner Deborah Clark	Group Art Unit 1633

☒ Responsive to communication(s) filed on *Oct 1, 1998* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *44-51, 62-64, 67-72, 74, and 78-89* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *44-51, 62-64, 67-72, 74, and 78-89* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response

1. Applicant's response to the previous office action has been received, 10/01/98, and entered, paper no. 31. Claims 44-51, 62-64, 67-72, 74, and 78-89 remain pending.

Claim Rejections - 35 USC § 112

2. Claims 44-51, 62-64, 67-72, 74, and 78-89 stand rejected under 35 USC 112, 1st paragraph. (Previously contained a typographical error which excluded claims 67 and 68).

Applicant's argue that the constructs used in the declaration filed 02/28/96 are 'essentially' the same as those described by the specification. Applicant's point to example 13. It is pointed out that the JW4303 based vectors are different. The size of the envelope fragments are not the same as those in the declaration. Given the data in the declaration and comparing to the data in the specification, it is not clear exactly all the differences used in the making of the constructs. However, the size is obviously different, re-sgp110 and sgp130 vs. sgp120 and sgp140.

Applicants argue that the SIV constructs are similar to the HIV constructs disclosed in the specification, example 12, and that this data in addition to the immune response achieved in the mice in example 12 would lead one to assume that the HIV constructs would have the same effect as the SIV constructs. However, the constructs used in example 12 bear different, though similar,

names. It is not clear that these mice were inoculated with the construct described at page 46 or a different construct. Further, the SIV/Rhesus model is not an art accepted model for predictions of efficacy into the HIV/human model. Furthermore, the data presented in the declaration do not demonstrate protectivity. It is not clear whether any of the monkeys, control or vaccinated, progressed to AIDS. The intended use of the claimed composition as well as the method of immunizing requires protection. Protection is not taken to mean a reduction in viral load or a particular immune response, but rather, a change in the susceptibility to the disease vaccinated against.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 46-49 and 71-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46-49 recite that the antigen 'represents' different subgroups, different phases of infection, different tropisms, or different routes of transmission. Claims 71 and 72 recite that the antigen is from a different phase of infection or a different route of transmission. It is not clear how an antigen, which is a protein, is going to 'represent' these characteristics or how one would be able to ascertain that an antigen is from a different phase or route. An antigen does not change in different phases of infection or in different routes of transmission. Though different antigens

may be present at different times or may be prevalent or non-prevalent depending upon the phase of infection or route of transmission, the claims are not worded to reflect this. It is not clear whether applicants is limiting the antigens to be different or whether one may be an env protein from an early phase of infection and the other the same env protein, but from a later phase of infection. Amendment to clarify the claims is required.

Claim Rejections - 35 USC § 102

5. The previously made rejections under 35 USC 102 (e) are withdrawn. It is acknowledged that the sited example in the art demonstrates inoculation with mRNA whereas the claims require DNA.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 44, 51, and 81-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al., US 5,693,622 or Felgner et al., US 5,703,055.

Wolff et al. and Felgner et al. disclose and demonstrate inoculation of mice with mRNA coding for the HIV nef protein (see example 9). Wolff et al. and Felgner et al. disclose and

demonstrate inoculation of mice with DNA encoding gp120 (see example 19). In example 9 a reduction in infected cells was demonstrated. In example 19 IgG and IgM antibodies were detected. Wolff et al. and Felgner et al. disclose that DNA or RNA sequences may be used when practicing the invention (see throughout, for instance at columns 5 lines 27-28 and 6 lines 46-47 of Wolff et al. and columns 6 line 16 and 9 lines 52-53 of Felgner et al.) Wolff et al. nor Felgner et al. demonstrates inoculation with DNA which results in protection from the virus. However, the inoculation with mRNA in example 9 demonstrates a protective effect. It is clear from the specification that Wolff et al. and Felgner et al. expect inoculation with DNA to work as well. One of skill in the art is motivated to substitute DNA for the mRNA where a longer duration of expression is desired (see column 12, lines 31-35 of Felgner et al. and column 9 lines 23-27 of Wolff et al.). Therefore, it would have been *prima facie* obvious at the time the invention was made to use DNA encoding the nef protein or the gp120 protein for immunization against HIV.

Wolff et al. and Felgner et al. also contemplate using liposome complexed DNA (see columns 21 and 22 of Wolff et al. and columns 24 and 25 of Felgner et al.) and many types of promoters (see columns 10 and 11 of Felgner et al. and column 7 of Wolff et al.) and numerous routes of administration (see column 23 lines 36-47 of Felgner et al. and column 20 lines 32-43 of Wolff et al.). Therefore, manipulation of the promoters, the route of administration, and formulations for delivery is considered to be obvious methods of routine optimization.

Conclusion

8. No claim is allowed.

9. Claims 45-50, 62-64, 67-72, 74, and 78-80 are free of the prior art of record because it was not disclosed or fairly suggested at the time the invention was made to inoculate with two or more DNA transcription units, with an antigen of SIV, or with the specific constructs listed in claims 62 and 68.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Clark whose telephone number is (703) 305-4051. The examiner can normally be reached on Mondays-Fridays from 7:10 a.m. EST to 3:40 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached on (703) 308-2801. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DRC

11-13-98

BRIAN R. STANTON
PRIMARY EXAMINER
GROUP 1800
1600